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Japan's Otsuka Pharma receives $17.8 M grant for TB drug trial

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Study expected to begin in 2022 evaluating safety and efficacy of novel 3-drug combination versus existing 4-drug standard of care



Otsuka Pharmaceutical Development & Commercialization, Inc., a subsidiary of Japan-based Otsuka Pharmaceutical, has been awarded a grant for up to $17.8 million from the Bill & Melinda Gates Foundation.

This will enable Otsuka to advance clinical trials of its investigational compound OPC-167832, in combination with its delamanid (DELTYBA® is the brand name where approved outside the U.S.) and Johnson & Johnson's bedaquiline (SIRTURO® is the brand name), for patients with drug-susceptible pulmonary tuberculosis (DS-TB).

OPC-167832 is an anti-TB compound that inhibits the enzyme Decaprenylphosphoryl-?-D-ribose 2'-oxidase (DprE1), which is connected to synthesis involving mycobacterial cell walls.

Employing a phase 2 design, the grant will support the investigation of a novel regimen in shortening the treatment of DS-TB by comparing the proportion of study subjects receiving the combination therapy for a duration of 4 months versus the 6-month standard of care. Decreasing treatment duration is likely to impact the number of patients treated and improve overall treatment adherence.

Specifically, the trial will compare the proportion of subjects with favorable outcome in each experimental treatment arm of OPC-167832, delamanid (DELTYBA) and bedaquiline (SIRTURO) as compared with patients receiving HRZE, a standard of care regimen of isoniazid (H), rifampicin (R), pyrazinamide (Z), and ethambutol (E).

The phase 2 trial of OPC-167832, delamanid (DELTYBA) and bedaquiline (SIRTURO) is expected to begin in 2022 with results available in 2024.